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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/823,142	GUILLAUME ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-75 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-75 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-75 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to a method for obtaining mastocytes comprising culturing bone marrow stem cells, classified in class 435, subclass 377.

II. Claim 9, drawn to porcine mastocytes that may be obtained from the method of Group I, classified in class 435, subclass 325.

III. Claims 10-16 and 22-47, drawn to porcine mastocytes with particular properties, classified in class 435, subclass 325.

IV. Claim 17, drawn to a porcine mastocyte line, classified in class 435, subclass 325.

V. Claim 18, drawn to another porcine mastocyte line, classified in class 435, subclass 325.

VI. Claim 19, drawn to another porcine mastocyte line, classified in class 435, subclass 325.

VII. Claim 20, drawn to another porcine mastocyte line, classified in class 435, subclass 325.

VIII. Claim 21, drawn to another porcine mastocyte line, classified in class 435, subclass 325.

IX. Claim 48, drawn to a method for culturing the mastocytes of Group III to produce heparin-type molecules, classified in class 435, subclass 325.

X. Claim 49, drawn to a method for producing heparin-type molecules by culturing porcine mastocytes, classified in class 435, subclass 325.

XI. Claim 50, drawn to another method for producing heparin-type molecules by culturing porcine mastocytes, classified in class 435, subclass 325.

XII. Claim 51, drawn to another method for producing heparin-type molecules by culturing porcine mastocytes, classified in class 435, subclass 325.

XIII. Claims 52 and 53, drawn to a protein of porcine origin of the c-kit type, classified in class 514, subclass 2+.

XIV. Claims 54-58, drawn to a nucleic acid encoding a protein of porcine origin of the c-kit type, classified in class 536, subclass 22.1+.

XV. Claim 59, drawn to a cell expressing a protein of porcine origin of the c-kit type, classified in class 435, subclasses 325+, 410+, or 243+.

XVI. Claims 60 and 61, drawn to a protein of porcine origin exhibiting 3-O-sulfatase activity, classified in class 514, subclass 2+.

XVII. Claims 62-66, drawn to a nucleic acid encoding a protein of porcine origin exhibiting 3-O-sulfatase activity, classified in class 536, subclass 22.1+.

XVIII. Claim 67, drawn to a cell expressing a protein of porcine origin exhibiting 3-O-sulfatase activity, classified in class 435, subclasses 325+, 410+, or 243+.

XIX. Claims 68 and 69, drawn to a protein of porcine origin exhibiting 6-O-sulfatase activity, classified in class 514, subclass 2+.

XX. Claims 54-58, drawn to a nucleic acid encoding a protein of porcine origin exhibiting 6-O-sulfatase activity, classified in class 536, subclass 22.1+.

XXI. Claim 59, drawn to a cell expressing a protein of porcine origin exhibiting 6-O-sulfatase activity, classified in class 435, subclasses 325+, 410+, or 243+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Group II (porcine mastocytes) may be made by a materially different process, *e.g.* by isolating mastocytes directly from pigs. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions III and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the mastocytes of Group III could be used in a materially different process, for example in *in vitro* studies of mastocyte growth and response to various pharmaceuticals. Because

these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions II-VIII are directed to various populations of porcine mastocytes; inventions XIII, XVI, and XIX are directed to various proteins; inventions XIV, XVII, and XX are directed to various nucleic acids; and inventions XV, XVIII, and XXI are directed to various cells that express proteins. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). These four types of products (mastocytes, proteins, nucleic acids, and unspecified cells) are distinct from each other because they do not overlap in scope, they are not obvious variants of each other, and they have materially different functions and effects.

The seven different populations of mastocytes are distinct from each other because they are not claimed as overlapping in scope or being obvious variants of each other. Groups II and III are drawn simply to mastocyte populations, not necessarily **isolated** mastocyte populations; Groups IV-VIII require that the mastocytes be isolated and cultured clonally from the animal. The mastocytes of Group II are not identical as claimed to the mastocytes of Group III, because claim 9 is silent on, for example, the characterization of the heparin-type molecules within the mastocytes of Group II. Groups IV-VIII are drawn to five deposited lines of mastocytes, which must be

interpreted as being distinct from each other by virtue of the fact that they have five distinct accession numbers and, presumably, distinct properties.

The three different proteins are distinct from each other because they have distinct sequences, functions, and effects. Similarly, the three different nucleic acids are distinct from each other because they have different sequences that encode distinct proteins.

The three different types of cells are distinct from each other because they each express one of three distinct proteins. Furthermore, these cells are distinct from the mastocytes of Groups II-VIII because the cells of Groups XV, XVIII, and XXI are not claimed as being animal cells, much less as porcine mastocytes. The Groups do not necessarily overlap in scope.

For at least these reasons, the sixteen products instantly claimed are distinct from each other. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions IX-XII are drawn to various methods of culturing mastocytes. Group IX requires culturing the mastocytes of Group III; Group X requires culturing any mastocytes (including those of II-VIII and any other mastocytes) in a particular medium; Groups XI and XII require different starting materials (mastocytes overexpressing IL-4 and mastocytes transfected with a nucleic acid encoding IL-4) than each other and than Groups IX and X. Group XII does not require that the mastocytes overexpress IL-4, only that they comprise a nucleic acid encoding IL-4. For at least these reasons, the four

processes of using mastocytes instantly claimed are distinct from each other. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions III-VIII and XIII-XIX are unrelated to Invention I. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to a method (Invention I) that does not necessarily make the recited products (Inventions III-VIII and XIII-XIX). Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions II, IV-VII, and XIII-XIX are unrelated to Inventions X-XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to various methods (Inventions X-XII) that do not necessarily require the recited products (Inventions II, IV-VII, and XIII-XIX). Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Invention I is unrelated to Inventions IX-XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to a method of making a product (Invention I) that is not free of the art and is not necessarily required for the methods of use (Inventions IX-XII). Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species:

Source of stem cells: (a) porcine bone marrow and (b) human fetal bone marrow, as in claims 5-8, for example; elect ONE if Group I is elected.

Genetic status of mastocytes: (c) transfected with an exogenous construct and (d) not transfected with any exogenous construct, as in claims 22-47, for example; elect ONE if any of Groups II-VIII is elected.

Products of exogenous constructs: (e) an immortalizing protein, (f) c-kit, (g) T antigen, (h) an enzyme that acts on the sulfation of the heparin-type molecules, and (i) 3-OST, as in claims 22-47, for example; elect ONE if Group III is elected.

The species are distinct because none is rendered obvious by the others in its group and because the disclosure does not connect them by any design, operation, or effect. See M.P.E.P. § 806.04(b). A requirement for restriction is permissible if there is a patentable difference between the species as claimed and there would be a serious burden on the examiner if restriction is not required. See M.P.E.P. § 808.01(a). In this case, considering enablement, utility, and description issues for each claimed species,

as well as conducting a thorough search of the prior art for each and every combination embodied by the present claims, would pose a serious burden to the examiner.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-21 are generic to at least one of these groups of species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. 1.116; amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35U.S.C. §§101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to maintain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the protection against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lora E Barnhart

LEB

SANDRA E. SAUCIER
PRIMARY EXAMINER